K002984

DEC 1 8 2000

510(k) Summary

CyberCare, EHC400 Desktop Patient Station
CyberCare, EHC600 Care Provider Station
CyberCare Electronic Stethoscope

The following information is submitted in accordance with 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: J. Terry Drury, Senior Vice President

Date Prepared September 22, 2000

Name of Device

CyberCare EHC400 Desktop Patient Station /EHC600 Care Provider Station

Device Classification/Classification Panel

21 CFR 870.1130 DXN Class II
Noninvasive Blood Pressure Measuring Systems

21 CFR 880.2910 FLL Class II
Clinical Electronic Thermometer

21 CFR 870.2700 DQA Class II
Noninvasive Pulse Oximeters

Cardiovascular Series Panel

Predicate Device

CyberCare EHC400 Desktop Patient Station/EHC600 Care Provider Station, E-Scope™ Electronic Stethoscope and the 3M Littmann Electronic Stethoscope.

Intended Use

The CyberCare EHC400 Desktop Patient Station (EHC400) is a patient monitoring system intended for providing out-of-hospital vital signs monitoring of adult patients or pediatric patients

with the assistance and supervision of an adult. The EHC400 is intended to work in conjunction with the EHC600 Care Provider Station (EHC600) providing two-way video, audio and data communication between the two stations. The EHC400 provides the following physiologic functions: noninvasive blood pressure (NIBP), oximeter (SpO_2), heart rate, electronic oral thermometer and an electronic stethoscope.

Description of the Device/Substantial Equivalence

The Company's EHC400, with electronic stethoscope, covered by this submission, is substantially equivalent to the predicate CyberCare EHC400 Desktop Patient Station (EHC400) that has already been cleared by FDA, pursuant to K000237. The EHC400 with electronic stethoscope has the same general intended use, same principles of operation, and same technological characteristics as the EHC400. The EHC400 with electronic stethoscope and its predicate device are both intended for providing out-of-hospital vital signs monitoring of adult patients, or pediatric patients with the assistance and supervision of an adult. They both consist of a touch screen computer and a vital signs unit providing monitoring of noninvasive blood pressure (NIBP), oximeter (SpO_2), heart rate, and electronic oral thermometer. The difference is the addition of an electronic stethoscope feature. The operating software of the EHC400 with the electronic stethoscope is the same as for the EHC400 predicate device.

The EHC400, installed where the patient can conveniently access it, is designed to be used with the EHC600, which is also cleared as part of K000237, remotely located at the office of a professional care provider. The two stations modem connected by standard phone lines or a digital transmission service provide real-time audio and video communication between the patient and the caregiver. Blood pressure, blood oxygenation saturation and pulse rate, oral temperature and electronic stethoscope allowing the system to amplify heart, breath, and bowel sounds
are transmitted over the communication link for display on the EHC600.

Performance Data

The EHC400 with electronic stethoscope uses currently available technology found in legally marketed devices. Testing, to ensure that the EHC400 with electronic stethoscope would perform as intended, was conducted at two levels: Non-clinical bench testing to test each function and clinical testing using volunteers to verify performance of the electronic stethoscope.

The EHC400 with electronic stethoscope and the EHC600 meets applicable standards for performance and EMC compliance.

Non-clinical Testing

Testing was performed to evaluate the three functional modules within the predicate EHC400. These tests were repeated on the EHC400 containing the electronic stethoscope The testing shows that the vital signs modules in the EHC400 with the electronic stethoscope operate substantially the same as those in the predicate EHC400.

Clinical Testing

Clinical testing was performed on 25 volunteer subjects under an appropriate IRB approved protocol. All stethoscope comparisons were taken with the individual seated adjacent to the Patient Desktop Station (EHC400) in a normal operating environment. The testing shows that the CyberCare Electronic Stethoscope functions favorably when compared to an ordinary stethoscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2000

Mr. J. Terry Drury
Executive Vice President
CyberCare Technologies, Inc.
7840 Roswell Road
Building 300, Suite 320
Atlanta, GA 30350

Re: K002984
CyberCare EHC400 & EHC600 Desktop Patient Stations
Regulatory Class: II (two)
Product Code: 74 DQD
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Drury:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

Indications for Use Form

510(k) Number (if known): K002984

Device Name: CyberCare EHC400 desktop Patient Station/
EHC600 Care Provider Station

Indications for Use:
The CyberCare EHC400 is a patient monitoring system intended for providing out-of- hospital vital signs patient monitoring. The system works in conjunction with the CyberCare EHC 600 Care Provider Station providing two-way video, audio and data communication between the two stations. The system monitors the following physiologic functions: blood pressure (sphygmomanometer), Oxygen saturation (pulse oximeter), heart rate (pulse oximeter), and temperature (electronic oral thermometer) and an electronic stethoscope which allows the system to amplify heart, breath, and bowel sounds.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002984

Prescription Use __ ___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)